We claim:

1. A process for manufacturing, in an aqueous medium, a controlled release excipient consisting primarily of cross-linked high amylose starch, for use in preparation of tablets, said process comprising

   (a) cross-linking high amylose starch thereby forming a reaction medium containing a reaction product consisting of a cross-linked high amylose starch slurry;

   (b) subjecting said cross-linked high amylose starch slurry from step (a) to chemical modification at a temperature of about 10 to about 90 °C for about 1 to about 72 hours;

   (c) neutralizing said reaction medium obtained in step (b) with an acid, washing the slurry formed and optionally dewatering or to form a starch cake or a dry powder;

   (d) diluting said slurry or re-slurrifying said starch cake or said dry powder from step (c) with water to form a slurry at a concentration of about 2% to about 40% w/w, adjusting pH to a desired value between about 3 and about 12, and gelatinizing said slurry at a temperature of about 80 to 180 °C for about 1 second to about 120 minutes; and

   (e) drying the thermally treated product obtained in step (d) to obtain said controlled release excipient consisting mainly of chemically modified and cross-linked high amylose starch in form of a powder.

2. The process according to claim 1, wherein steps (a) and (b) are performed at the same time.

3. The process according to claim 1 comprising,

   (a) cross-linking high amylose starch containing at least 70% w/w of amylose with about 0.005g to about 0.3 g cross-linking reagent per 100 g of dry-based high amylose starch in an aqueous medium at a temperature of about 10 to about 90°C thereby forming a reaction medium containing a reaction product consisting of a cross-linked high amylose starch slurry;

   (b) subjecting said cross-linked high amylose starch slurry from step (a) to hydroxypropylation with propylene oxide at a temperature of about 10 to

about

90 °C for about 1 to about 72 hours to yield a reaction medium containing a hydroxypropylated cross-linked high amylose starch slurry;

(c) neutralizing said reaction medium obtained in step (b) with a dilute aqueous acid, washing slurry formed and optionally dewatering to obtain a starch cake or a dry powder;

(d) diluting said slurry, or re-slurrifying starch cake or dry powder from step (c) with water to form a slurry at a concentration of about 2% to about 40% w/w, adjusting pH to about 4.0 to about 9.0, and gelatinizing said slurry formed in current step at a temperature of about 80 to about 180 °C for about 1 second to about 120 minutes; and

(e) drying said thermally treated product obtained in step (d) to obtain said controlled release excipient consisting mainly of hydroxypropylated and cross-linked high amylose starch in form of a powder.

4. The process of claim 3, wherein, in step (a), said cross-linking reagent is phosphorous oxychloride in an amount of between about 0.01 and about 0.2 g per 100 g starch dry basis or sodium trimetaphosphate in an amount of between about 0.05 and about 0.3 g per 100 g starch dry basis..

5. The process of claim 3 wherein step (a) is performed in an aqueous alkaline medium.

6. The process of claim 4, wherein, in step (a), said cross-linking is carried out at a pH of about 10 to about 14 and at a temperature of about 15 to about 90 °C for about 0.2 to about 40 hours.

7. The process of claim 3, wherein, in step (b), said hydroxypropylation is carried out with up to 10% propylene oxide at a temperature of about 40 to about 80 °C for about 10 to about 72 hours.

8. The process of claim 3, wherein, in step (c), said neutralization of said reaction medium is carried out with dilute sulfuric acid or hydrochloric acid.

9. The process of claim 3, where, in step (d), said gelatinization is carried out by direct steam injection into an aqueous suspension of said cross-linked high amylose starch.

10. The process of claim 3, wherein, in step (d), said pH is adjusted to about 6.0 and said temperature is kept at about 80 to about 180 °C for about 2 to about 10 minutes.

11. The process of claim 3, wherein, in step (e), said drying is carried out by spray-drying.

12. The process of claim 11, wherein, in step (e), inlet temperature is from about 60 to about 350 °C, and outlet temperature is set from about 40 to about 210°C.

13. A process for manufacturing, in an aqueous medium, a controlled release excipient consisting primarily of cross-linked high amylose starch, for use in preparation of tablets, said process comprising

(a) subjecting high amylose starch to chemical modification at a temperature of about 10 to about 90 °C for about 1 to about 72 hours thereby forming a reaction medium containing a chemically modified high amylose slurry;

(b) cross-linking said chemically modified high amylose starch in said slurry obtained in step (a);

(c) neutralizing said slurry obtained in step (b) with an acid, washing the slurry formed and optionally dewatering to form a starch cake or drying to form dry powder;

(d) diluting said slurry, or re-slurrifying said starch cake or said dry powder from step (c) with water to form a slurry at a concentration of about 2% to about 40% w/w, adjusting pH to a desired value between about 3 and about 12, and gelatinizing said slurry at a temperature of about 80 to 180 °C for about 1 second to about 120 minutes; and

(e) drying the thermally treated product obtained in step (d) to obtain said controlled release excipient consisting mainly of chemically modified and cross-linked high amylose starch in form of a powder.

14. The process according to claim 13, wherein steps (a) and (b) are performed at the same time.

15. The process according to claim 13 comprising

(a) subjecting high amylose starch containing at least 70% w/w of amylose to hydroxypropylation with propylene oxide at a temperature of about 10 to about

90 °C for about 1 to about 72 hours to yield a reaction medium containing a reaction product of consisting primarily of a hydroxypropylated high amylose starch slurry;

(b) cross-linking said hydroxypropylated high amylose starch slurry with about 0.005g to about 0.3 g cross-linking reagent per 100 g of dry-based high amylose starch in an aqueous medium at a temperature of about 10 to about 90 °C to yield a reaction medium containing a cross-linked hydroxypropylated high amylose starch slurry;

(c) neutralizing said reaction medium obtained in step (b) with a dilute aqueous acid, washing slurry formed and optionally dewatering to obtain a starch cake or a dry powder;

(d) diluting said slurry, or re-slurrifying said starch cake or said dry powder from step (c) with water to form a slurry at a concentration of about 2% to about 40% w/w, adjusting pH to about 4.0 to about 9.0, and gelatinizing said slurry formed in current step at a temperature of about 80 to about 180 °C for about 1 second to about 120 minutes; and

(e) drying said thermally treated product obtained in step (d) to obtain said controlled release excipient consisting mainly of hydroxypropylated and cross-linked high amylose starch in form of a powder.

16. The process of claim 15, wherein, in step (a), said cross-linking reagent is phosphorous oxychloride in an amount of between about 0.01 and about 0.2 g per 100 g starch dry basis or sodium trimetaphosphate in an amount of between about 0.05 and about 0.3 g per 100 g starch dry basis.

17. The process of claim 15 wherein step (b) is performed in an aqueous alkaline medium.

18. The process of claim 16, wherein, in step (b), said cross-linking is carried out at a pH of about 10 to about 14 and at a temperature of about 15 to about 90 °C for about 0.2 to about 40 hours.

19. The process of claim 15, wherein, in step (a), said hydroxypropylation is carried out with up to 10% propylene oxide at a temperature of about 40 to about 80 °C for about 10 to about 72 hours.

20. A controlled release tablet comprising a compressed blend of at least two dry powders, including a powder of at least one pharmaceutical agent and a powder of a controlled release excipient;

wherein said controlled release excipient comprises a chemically-modified, cross-linked high amylose starch prepared by a method comprising:

(a) cross-linking high amylose starch, followed by

(b) chemically modifying the cross-linked high amylose starch, followed by

(c) gelatinization, and

(d) drying to obtain a powder of said controlled release excipient;

wherein said cross-linked high amylose starch is characterized in that upon solubilization in 90% DMSO at 80 °C for about three days and gel permeation chromatography, the height of the peak corresponding to amylose in said cross-linked high amylose starch is at least 90% of that of the peak corresponding to amylose in said high amylose starch prior to (a).